II. Amendments to claims 1, 6, 7 and 13-15 and new claim 20

Amendments to the claims are supported by the specification as follows:

Support for the limitation "unrelated to contractures or spasticity" and patients "not having contractures or spasticity" in claims 1, 6, 7 and 13 can be found at least in the narrative on page 23, lines 14-15 and in the narratives describing treatment of pressure sores unrelated to contractures or spasticity in Examples 1, 2, 4, and 5 of the specification, which describe the development of pressure sores in patients that do not suffer contractures or spasticity.

Support for the amendment "wherein the therapeutically effective amount of a botulinum toxin is less than an amount that would be used to paralyze a muscle" in claims 1, 6, 7 and 13, which clearly define pressure sores that develop/are present when the condition is not associated with spasticity or contractures, can be found at least in the narrative at page 23, lines 14-18 of the specification.

Support for the amendment "occurring in an area as a result of pressure from lying in bed or sitting in a wheelchair" in claim 15 can be found in the disclosure at least at page 1, lines 22-28 and in the disclosure of Examples 1 and 2, which describe the development of pressures sores from lying in bed. This disclosure also supports the recitation of a pressure sore that is a result of immobility of the patient not having contractures or spasticity in claim 14.

New claim 20 is added, support for which can be found at least in the narratives detailed above, where methods of treatment of pressure sores unrelated to muscle spasms, by the administration of botulinum toxin in amounts that do not paralyze a muscle, are disclosed.

III. Rejection of claims 15-18 under 35 U.S.C. 102(b)

The Office Action rejected claims 15-18 under 35 U.S.C. 102(b) as being anticipated by Pohl et al. Applicant traverses this rejection.

Claims 15-18 have been amended to positively recite and narrowly define the patient as a patient not having contractures or spasticity, in the body of the claim, as suggested on page 3 of the Office Action. Additionally, amended claims 15-18 now define the pressure sore being treated as occurring in an area as a result of pressure from lying in bed or sitting in a wheelchair and is not related to contractures or spasticity and further recite a correlation step ("thereby treating a pressure sore occurring in an area as a result of pressure from lying in bed or sitting in a wheelchair and that is not related to contractures or spasticity) that corresponds to the preamble of the amended claim 15.

Pohl et al. is specifically and narrowly directed to the treatment of pressure ulcers that arise in patients suffering spasticity the treatment including serial casting (Objective page 35, left col.) and paralyzing the spastic muscles and administering systemic anti-spastic therapy (page 37, left col.).

Nowhere in Pohl et al. can the teachings or suggestion of treatment of pressure sores that arise as a result of pressure from lying in bed or sitting in a wheelchair, nor can the treatment of administering botulinum toxin to pressure sores in non-spastic patients, be found.

Since Pohl et al. does not teach or disclose each limitation found in the newly amended claims 15-18, Pohl et al. cannot anticipate the claims.

Thus, the rejection should be withdrawn.

IV. Rejection of claims 15-17 under 35 U.S.C. 102(b)

The Office Action rejected claims 15-17 under 35 U.S.C. 102(b) as being anticipated by Kennedy (1997). Applicants traverse the rejection.

The disclosure of Kennedy is limited to the use of botulinum toxin injected into spastic muscles to treat cramping and to reduce spasms in muscles. Contrarily, the currently amended claims 15-17 limit the patient in which the pressure sore are treated as "not having contractures or spasticity", in the body of the claim, and further define the pressure sore being treated as occurring in an area as a result of pressure from lying in bed or sitting in a wheelchair. Additionally, the method step does correlate to the recited intended use of the claimed methods, that is, treating pressure sores that are unrelated to contractures or spasticity.

Kennedy does not disclose the administration of a botulinum toxin to treat pressure sores in a patient not having contractures or spasticity and thus cannot anticipate the currently amended claims.

Thus, the rejection should be withdrawn.

V. Rejection of claims 7-11 under 35 U.S.C. 102(b)

The Office Action rejected claims 7-11 under 35 U.S.C. 102(b) as being anticipated by Gassner et al., U.S. patent 6,447,787 ("Gassner"). Applicants traverse the rejection.

Respectfully, the Office Action has misconstrued Gassner and the wounds that are the subject of the disclosed treatments which are directed to improving the cosmetic appearance of healed wounds (col. 2, lines 56-62). Gassner is directed to minimizing the formation of scar tissue during the healing of wounds, both traumatic and iatrogenic (physician-induced), by *paralyzing* muscles capable of exerting tension on the wounds (col. 1, lines 59-65). Additionally, an "unfavorable wound", as defined in Gassner, is *not* a region of inflamed skin that needs wound healing, as stated by the Office Action, but is instead a wound that is oriented relatively perpendicularly to a relaxed skin tension lines (RSTL) (col. 3, lines 16-18). Relaxed skin tension lines are lines along the body that delineate lines that follow furrows formed when the skin is relaxed. Incisions made parallel to these tension lines (favorable wound) heal better than those made tangentially to tension lines (unfavorable wound) (see attached illustration from Family Practice Notebook website).

Such disclosures teach away from the claim methods. A reference which teaches away from a claimed invention cannot be used to reject a claim. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) ("...the district court erred in...disregarding disclosures in the references that diverge from and teach away from the invention at hand." 220 USPQ at 311) (copy attached).

Amended claim 7 recites the limitation of administering botulinum toxin in therapeutically effective amount that is less than an amount that would be used to paralyze a muscle, which is opposite of the teachings of Gassner (col. 1, lines 62-67; col. 2, lines 56-58). Since such a limitation cannot be found in Gassner, and Gassner teaches away from the claimed methods, Gassner cannot anticipate nor render obvious the amended claims.

Thus, the rejection should be withdrawn.

VI. Rejection of claims 1-11, 13-14 under 35 U.S.C. 112, first paragraph

The Office Action rejected claims 1-11, 13-14 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement, more particularly, for reciting the phrase "without reducing spasticity of a muscle, thereby treating a pressure sore'. Applicant traverses this rejection.

Claims 1, 6, 7 and 13 have had the phrase "without reducing spasticity of a muscle" deleted therefrom and have the added limitation of administration of an "amount of a botulinum toxin is less than an amount that would be used to paralyze a muscle"; the claims further defining the patient as not having contractures or spasticity, support for which can be found at least in the narrative at page 23, line 14-18 of the specification.

Thus, the rejection should be withdrawn.

VII. Rejection of claims 1-11, 13-19 under 35 U.S.C. 112, first paragraph

The Office Action rejected claims 1-11, 13-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that the claimed invention is not enabled for the administration of doses of about 3000 units or more to a patient in the claimed methods for treating a pressure sore or preventing a pressure sore. Applicant traverses this rejection.

It appears that only claims 4, 10 and 18 are subject to this rejection, as they are the only claims that recite units of botulinum administered to treat or prevent pressure sores. Therefore, Applicant is assuming that claims 1-3, 5-9, 11, 13-17 and 19 are not under this rejection.

The claims which recite various doses of administered botulinum toxin are clearly enabled. Respectfully, Brin states that the lethal dose in humans is not known (see page S155, col. 2, paragraph 2) but that based on extrapolation, a parenteral LD_{50} dose, of *botulinum toxin type A* would be nearly 3000 units. The inventors of the present invention have discovered that various botulinum serotypes at various doses can be utilized to treat pressure sores in accordance with the teachings of the present invention.

For example, based on factors such as size, weight, and responsiveness to therapy (all typical medical parameters known to those of skill in the art) the amount and type of toxin administered can vary (see page 34 of the specification, as an example). The safe administration of botulinum toxin to human patients, in the tens of thousands of units, was known in the art (see attached Mov Disord 2002;17 (Suppl 5):S292 ABS P961) which discloses the safe administration of up to 25,000 units of botulinum toxin (see last paragraph) and provides further proof that the recited range of units of botulinum toxin administration are enabled by what was known in the art, as well as by the instant specification.

Thus, the rejection should be withdrawn.

VIII. Rejection of claims 7-11 and 15-19 under 35 U.S.C. 102(b)

The Office Action has rejected claims 7-11 and 15-19 under 35 U.S.C. 102(b) as being anticipated by Borodic (PG-Pub 2002/017164) ("Borodic"). Applicant traverses this rejection.

Respectfully, the Office Action has misconstrued the disclosure and teachings of Borodic. The composition disclosed and administered in Borodic are not botulinum neurotoxins, but rather an altered protein derived from Clostridium botulinum that *lacks neurotoxin properties*, and are not utilized to treat or prevent pressure sores. Furthermore, a detailed reading of the disclosure of Borodic shows no disclosure relating to wounds or sores, let alone pressure sores. Respectfully, inflammation that is referenced in this disclosure is related to allergic reactions, as detailed at paragraph [0018] where an allergic reaction (inflammatory response) after exposure to ragweed pollen is discolored, and not to a pressure point. This is not surprising since the Borodic disclosure is not directed to wound or sore treatment or prevention in any way.

Since Borodic does not disclose treatment of a pressure sore occurring in an area as a result of pressure from lying in bed or sitting in a wheelchair and that is not related to contractures or spasticity (claim 15) nor administration at pressure point of a patient not having contractures or spasticity (claim 7), Borodic cannot anticipate the instant claims.

Thus, the rejection should be withdrawn.

IX. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 1-11 and 13-19 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/CLAUDE L. NASSIF/

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Attached: W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)
Mov Disord 2002:17(Suppl 5):S292ABS P961
Family Practice Notebook webpage re Relaxes Skin Tension Lines